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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,579	12/27/2000	Alan Ebringer	092620269448	1579

7590 09/27/2002

Joseph T Leone
Intellectual Property Department
Dewitt Ross & Stevens SC
800 Excelsior Drive Suit 401
Madison, WI 53717-1914

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/27/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,579

Applicant(s)

EBRINGER, ALAN

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7May2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1645

DETAILED ACTION

1. Please note that the Patent Examiner of your application in the PTO has changed. All communications should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (703)308-4244.
2. Applicant's Response to Office Action, received 7May2002, paper#11, is acknowledged. Claims 5-7 and 9-14 have been amended.
3. Claims 1-15 are pending and under consideration.

Drawings

4. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it claims priority from PCT/GB97/02267. This PCT number appears to be in error and should be PCT/GB97/02667.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Art Unit: 1645

7. The disclosure is objected to because of the following:
- a) the priority statement (see preliminary amendment) claims priority from PCT/GB97/02267. This PCT number appear to be in error and should be PCT/GB97/02667.

Appropriate correction is required.

Rejections/Objections Withdrawn

8. The objection to claims 10-14 for not reciting a required Sequence Identification Number is withdrawn in light of the amendment of the claims.
9. The rejection of claims 1, 8, 19, and 13 under 35 U.S.C. §112, second paragraph, indefiniteness, is withdrawn.
10. The rejection of claims 1-15 under 35 U.S.C. §103(a) as being unpatentable over Prusiner et al (U.S. Pat. No. 5,565,186) in view of Hartnett et al (*J. Bacteriol.*, 172(2):956-966, 1990), and further in view of Marchalonis et al (*Antibody as a Tool*, Chapters 2-3 and 13-14, J. Wiley & Sons, UK, 1982) is withdrawn.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Art Unit: 1645

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 2, 4, 5, 6, 10, 11, and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-17, 20-29, 32-41, and 44-51 of copending Application No. 09/269,607. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to method of detecting/diagnosing spongiform encephalopathy/multiple sclerosis in mammals comprising measuring a sample from said mammal for antibodies which bind to *Acinetobacter*.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1645

Claim Rejections - 35 USC § 112

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using whole *Acinetobacter calcoaceticus* as the antibody binding indicator for multiple sclerosis, Creutzfeldt-Jakob disease, and bovine spongiform encephalopathy, does not reasonably provide enablement for purified/isolated individual antigens of *Acinetobacter calcoaceticus*, or for diagnosis of other de-myelinating diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

The instant claims are drawn to methods and kits for detecting any de-myelinating disease or spongiform encephalopathy in mammals by assaying for IgA antibodies which bind to an *Acinetobacter* antigen.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of

Art Unit: 1645

experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - The instant claims are drawn to methods and kits for detecting any de-myelinating disease or spongiform encephalopathy in mammals by assaying for IgA antibodies which bind to an *Acinetobacter* antigen.

The state of the prior art - While *Acinetobacter calcoaceticus*, multiple sclerosis, Creutzfeldt-Jakob disease, and bovine spongiform encephalopathy are known in the art, the nexus correlating IgA anti-*Acinetobacter calcoaceticus* levels with multiple sclerosis, Creutzfeldt-Jakob disease, and bovine spongiform encephalopathy appears to be unique to the instant applicants.

The amount of direction or guidance present - The instant specification provides guidance and examples of only whole *Acinetobacter calcoaceticus* as the antibody binding indicator. There is no identification what antigen(s) are involved in the antibody binding. Therefore, the scope of the claims directed to individual antigens as indicators merely constitutes an invitation to experiment without a reasonable expectation of success that there is one and only one antigen at work.

The instant specification provides guidance and examples of whole *Acinetobacter calcoaceticus* as the antibody binding indicator for positive detection of only multiple sclerosis, Creutzfeldt-Jakob disease, and bovine spongiform encephalopathy. There is no indication of universal detection of all de-myelinating diseases. Without some indication of what

Art Unit: 1645

immunogen(s) in the diseases are inducing the IgA antibodies, the scope of the claims merely constitutes an invitation to experiment without a reasonable expectation of success that all demyelinating diseases induce/react with the same type of antibodies.

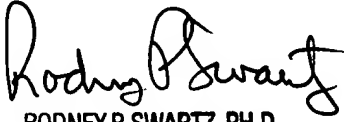
Conclusion

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

September 25, 2002